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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,510	06/23/2003	Patrick Quillin		9733

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/601,510	QUILLIN, PATRICK	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher R. Tate	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the initial phrase "aqueous solution for nasal use comprising the following ingredients in the ratio set forth:" because, firstly, it is unclear as to the intended use of the claimed aqueous solution - for nasal use as what (e.g., as an antimicrobial, as a nasal tissue moisturizer); and secondly, the phrase therein "in the ratio set forth" is somewhat unclear - e.g., are the ingredients in the ratio set forth below, set forth within the specification, or somewhere else? It is suggested that this phrase be amended to recite --An aqueous antimicrobial solution for nasal use comprising the following ingredients in the following ratio:-- or similar phraseology to more clearly define this phrase limitation.

Claims 1-3 are rendered vague and indefinite because it is unclear as to what the recited percentage ranges relate to - e.g., are these ranges defining percentage by weight, by volume, or something else? If these percentages are meant to be by weight, it is suggested that the phrase --, by weight-- follow each of the recited percentage ranges.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun Trading LTD (FR 2741535 - EPAB abstract), the PROMT Product Alert Bulletin of September 11, 2000 entitled "AloeDent Aloe Vera Mouthwash", Frank (US 6,454,754), and the admitted recognized state of the art.

A solution comprising percentage ranges of homeopathic *Baptisia tinctoria* (12x), colloidal silver, grapefruit seed extract, and oregano is claimed. Dependent claims include the solution further comprising saline (sodium chloride) and benzalkonium chloride.

The Sun Trading LTD reference beneficially teaches an antimicrobial aqueous, saline solution comprising oregano and benzalkonium chloride (see EPAB Abstract). This reference does not teach the other claimed ingredients. However, with respect to the homeopathic ingredient *Baptisia tinctoria*, 12x (which is expressly taught as representing a dilution of  $10^{-12}$  - see, e.g., bottom two paragraphs on page 3 of the instant specification), this ingredient is deemed to read upon water and/or saline (as taught by Sun Trading) since at this dilution level, it would not be conceivable that any active *Baptisia tinctoria* herbal agents remain therein (see, e.g., the enclosed 6-page reference by Dr. Stephen Barrett entitled "Homeopathy: The Ultimate Fake" with respect to such homeopathic dilution levels). Further, even if the claimed homeopathic *Baptisia tinctoria* is considered an active ingredient within the claimed solution, please note that Applicant readily admits that homeopathic *Baptisia tinctoria* is well known in the art as being an antimicrobial medicine (see, e.g., last paragraph on page 3 of the instant specification).

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The PROMT Product Alert bulletin beneficially teaches an aqueous antimicrobial mouthwash solution which comprises grapefruit seed extract as an active ingredient therein (see PROMT Abstract).

Frank beneficially teaches an aqueous antimicrobial solution comprising colloidal silver as an active ingredient therein (see entire document including col 1, line 11 - col 2, line 40; col 3, lines 36-41).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose (as antimicrobial agents) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients - i.e., it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960), In re Sussman, 1943 C.D. 518. The result-effective adjustment of particular conventional working conditions (e.g., determining result effective amount(s)/range(s) of such antimicrobial agents therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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From the teachings of the references as well as the admitted state of the art, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate  
Primary Examiner  
Art Unit 1654